General

Guideline Title

Transvaginal mesh procedures for pelvic organ prolapse.

Bibliographic Source(s)

Walter JE, Lovatsis D, Easton W, Epp A, Farrell SA, Girouard L, Gupta CK, Harvey MA, Larochelle A, Robert M, Ross S, Schachter J, Schultz JA, Wilkie DH. Transvaginal mesh procedures for pelvic organ prolapse. J Obstet Gynaecol Can. 2011 Feb;33(2):168-74. [36 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The quality of evidence (I-III) and classification of recommendations (A-L) are defined at the end of the "Major Recommendations."

1. Patients should be counselled that transvaginal mesh procedures are considered novel techniques for pelvic floor repair that demonstrate high rates of anatomical cure in uncontrolled short-term case series. (II-2B)
2. Patients should be informed of the range of success rates until stronger evidence of superiority is published. (II-2B)
3. Training specific to transvaginal mesh procedures should be undertaken before procedures are performed. (III-C)
4. Patients should undergo thorough preoperative counselling regarding (a) the potential serious adverse sequelae of transvaginal mesh repairs, including mesh exposure, pain, and dyspareunia; and (b) the limited data available comparing transvaginal mesh systems with traditional vaginal prolapse repairs or with traditional use of graft material in the form of augmented colporrhaphy and sacral colpopexy. (III-C)
5. Until appropriate supportive data are available, new trocarless kits should be considered investigative. (III-C)

Definitions:

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence from well-designed controlled trials without randomization.

II-2: Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research group.

II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Classification of Recommendations†

A. There is good evidence to recommend the clinical preventive action.

B. There is fair evidence to recommend the clinical preventive action.

C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making.

D. There is fair evidence to recommend against the clinical preventive action.

E. There is good evidence to recommend against the clinical preventive action.

L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making.

*Adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

†Adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Pelvic organ prolapse

Guideline Category

Counseling

Management

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Surgery

Urology

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide an update on transvaginal mesh procedures, newly available minimally invasive surgical techniques for pelvic floor repair

Target Population

Women who have pelvic organ prolapse

Interventions and Practices Considered

Minimally invasive transvaginal mesh (TVM) procedures for pelvic organ prolapse

Major Outcomes Considered

- Rates of anatomical cure
- Rates of anatomical failure (recurrent Pelvic Organ Prolapse Quantification System [POP-Q] stage II prolapse or greater)
- Complications of surgical procedure

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

PubMed and MedLine were searched for articles published in English, using the key words "pelvic organ prolapse," "transvaginal mesh," and "minimally invasive surgery." Results were restricted to systematic reviews, randomized control trials/controlled clinical trials, and observational studies. Searches were updated on a regular basis, and articles were incorporated in the guideline to May 2010. Grey (unpublished) literature was identified through searching the websites of health technology assessment and health technology assessment-related agencies, clinical practice guideline collections, clinical trial registries, and national and international medical specialty societies.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence from well-designed controlled trials without randomization.

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III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

*Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The quality of evidence was rated using the criteria described in the Report of the Canadian Task Force on the Preventive Health Care.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Classification of Recommendations†

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B. There is fair evidence to recommend the clinical preventive action.

C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making.

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†Adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This technical update was prepared by the Urogynaecology Committee and approved by the Executive of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of transvaginal mesh (TVM) procedures for patients with pelvic organ prolapse

Potential Harms

Postoperative complications from transvaginal mesh procedures include higher rates of mesh exposure than previous procedures, mesh shrinkage, and dyspareunia. Other potential complications include infection, pain, voiding dysfunction, pelvic floor dysfunction recurrence, and visceral or vascular perforation.

Qualifying Statements

Qualifying Statements

This document reflects emerging clinical and scientific advances on the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not was provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Feb

Guideline Developer(s)

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

Source(s) of Funding

Society of Obstetricians and Gynaecologists of Canada

Guideline Committee

Urogynaecology Committee

Composition of Group That Authored the Guideline

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BC

Financial Disclosures/Conflicts of Interest

Disclosure statements have been received from all members of the committee.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Society of Obstetricians and Gynaecologists of Canada Web site .

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on May 4, 2011. The information was verified by the guideline developer on June 6, 2011.

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